K05 1797

JUL 21 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
ZIP-Code, City:	D-82229 Seefeld
Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
Official Correspondent:	Dr. Andreas Petermann, Manager Regulatory Affairs
Phone:	011-49-8152-700 1395
Fax:	011-49-8152-700 1869
E-mail:	andreas.petermann@mmm.com
Date:	July 1, 2005

Name of Device

Proprietary Name:	Future Wash Light Body Future Wash Light Body Quick Step Future Wash Regular Body Future Wash Regular Body Quick Step YPS Penta™ HB Quick Step
Classification Name	Impression material
Common Name:	Dental impression material

Predicate Devices:

Future Wash Light Body, Future Wash Light Body Quick Step,
Future Wash Regular Body, Future Wash Regular Body Quick Step:

Dimension™ Garant™ L, K000588

YPS Penta HB Quick Step:

Dimension™ Penta™ H, K000591

Description for the Premarket Notification

Future Wash and YPS are classified as Impression materials (21 C.F.R. § 872.3660) because they are devices intended to reproduce the structure of a patient's teeth.

Future Wash will be available as wash material in two different viscosities (light body, regular body), each of them in a regular-set and a quick-set version, and YPS will be a tray material in a quick-set version.

3M ESPE is submitting this special 510(k) for modifications to its silicone impression materials Dimension™ Garant™ L and Dimension™ Penta™ H.

The Future Wash materials are two component (base paste/catalyst) materials designed to be used in 3M ESPE's mixing, dosing and dispensing device, Garant™. YPS is a two

component (base paste/catalyst) materials to automatically be mixed and dispensed in the 3M ESPE's Pentamix™ 2 device.

To provide evidence for safety biocompatibility testing was carried out. The results show that Future Wash and YPS are safe devices.

To prove the effectiveness of Future Wash and YPS, their performance characteristics were compared to those of the respective predicate devices.

In summary, Future Wash and YPS, described in this 510(k) premarket notification submission, are, in our opinion, substantially equivalent to the respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
Seefeld, D-82229
GERMANY

Re: K051797
Trade/Device Name: Future Wash and YPS Penta™
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 01, 2005
Received: July 05, 2005

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051797

Device Name: Future Wash (Future Wash Light Body, Future Wash Light Body Quick Step, Future Wash Regular Body, Future Wash Regular Body Quick Step)

YPS (YPS Penta™ HB Quick Step)

Indications For Use:

Future Wash (Future Wash Light Body, Future Wash Light Body Quick Step, Future Wash Regular Body, Future Wash Regular Body Quick Step):
Wash material for all kinds of dual phase impression techniques.

YPS (YPS Penta™ HB Quick Step):
Tray material for all kinds of dual phase impression techniques.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beck DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051797